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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/786,988 01/23/97 LITTLE

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IM22/1207

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EXAMINER

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ART UNIT

PAPER NUMBER

1743

20

DATE MAILED:

12/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
08/786,988

Applicant(s)
Little et al.

Examiner
Long V. Le

Group Art Unit
1743



☒ Responsive to communication(s) filed on Oct 19, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-6, 9-34, 40-51, and 54-90 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-6, 9-34, 40-51, and 54-90 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 13-16, 19

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

1. Applicants' cancellation of claims 7, 8, 35-39, 52 and 53; and addition of claims 91-101 are acknowledged and have been entered.

Claim Rejections - 35 USC § 112

2. Claims 100 and 101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 100 and 101 are vague and indefinite as to it is unclear what they are intended for since the array of samples have been recited in the independent claim. Additionally, the product claims do not further limit the steps recited of the method claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or unobviousness.

5. Claims 1-6, 9-34, 40-51, 54-69 and 87-101^{4c} are rejected again under 35 U.S.C. 103(a) as being unpatentable over Tisone (USP 5,743,960) in view of Patterson (USP 5,869,240).

Tisone discloses a method and an apparatus for dispensing a material on a substrate substantially as claimed. The method comprises the steps of providing a vesicle 12 having an interior chamber containing a fluid, disposing the vesicle 12 adjacent a first location on the surface of a substrate 30, controlling the vesicle to eject from the chamber a nanoliter volume of the fluid to dispense the fluid at the first location of the surface of the substrate, and moving the vesicle to a set of positions so that fluid is dispensed from the vesicle at each location of the set for forming an array of fluid material (figures 1, 6 and 7). Note that Tisone teaches in one of embodiments that the method can be used to dispense sample fluids onto a diagnostic test strip for testing (column 11, lines 14-25). Tisone does not specifically recite the step of performing mass spectrometry analysis for the material. However, such an analysis step on a substrate using a mass spectrometer is considered conventional in the art, see Patterson. Patterson teaches a method for sequencing polymers using a mass spectrometer in order to provide a rapid, automated and cost effective sequencing of polymers with a statistical certainty (Background and Summary of the Invention sections).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method and the apparatus of Tisone et al. with a spectrometer, as taught by Patterson, in order to provide a rapid, automated and cost effective sequencing of polymers with a statistical certainty.

6. Claims 70-86 and 94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ershow et al. (USP 5,756,050) in view of Patterson (USP 5,869,240).

Ershow et al. disclose a method for dispensing nanoliter volumes of a material on the surface of a substrate 16 substantially as claimed. The method comprises the steps of providing a pin assembly 1 having a plurality of elongated vesicles 2 arranged as an array for dispensing a liquid therefrom (figures 1 and 2), wherein each vesicle comprises a solid shaft of material having an end for retaining a nanoliter volume of fluid; loading a volume of fluid from a fluid source 14 onto the end of the vesicles; disposing the pin assembly to align the vesicles at a first set of locations adjacent to the surface of the substrate 16; and contacting the loading fluid to the surface of the substrate aligned with the vesicles, whereby an array of material on the surface of the substrate is formed (figures 3-4). Ershow et al. fail to specifically recite a diagnostic tool comprising of a mass spectrometer. However, the use of such a spectrometer for identifying polymers is considered conventional in the art, see Patterson (USP 5,869,240). Patterson teaches a method for sequencing polymers using a mass spectrometer in order to provide a rapid, automated and cost effective sequencing of polymers with a statistical certainty (Background and Summary of the Invention sections).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the method of Ershow et al. with a spectrometer, as taught by Patterson, in order to provide a rapid, automated and cost effective sequencing of polymers with a statistical certainty.

Response to Arguments

7. Applicants' arguments filed September 21, 1999 have been fully considered but they are not persuasive.

Applicants argue that Tisone does not teach or even suggest, of all possible available technologies, which type of analytical technology can be used to analyze the sample transferred by the aspirating operation. Applicants further argue that Tisone does not teach that such sample can be analyzed by mass spectrometry. The arguments are not persuasive. Firstly, the teaching of all available technologies is irrelevant to the issue because the claimed dispensing methods are clearly taught by Tisone. Secondly, the mass spectrometry is taught by Patterson which the Examiner relies on.

With respect to Patterson reference, Applicants contend that Patterson does not teach or suggest combining mass spectrometry analysis with arrays of samples produced by dispensing nanovolumes, nor that it is advantageous to perform mass spectrometry on an array of samples of a size that results from dispensing nanoliter volumes of material on a substrate. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants further argue that the combination of teachings of the cited references does not teach or suggest the unexpected results that derive from using arrays produced by dispensing nanoliter volumes of sample for mass spectrometric analyses. This argument is not persuasive because the claimed volume range of sample is taught by Tisone. Further, one of ordinary skill in the art would recognize that such a low volume sample dispensing offers several advantages such as dispensed volume accuracy and uniformity, as well as elimination of wasting expensive samples or reagents, etc.

With respect to the declaration, it has been fully considered but is not persuasive since Applicant has not discussed the applied references upon which the Examiner relies.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Long V. Le whose telephone number is (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.



Long V. Le
Primary Patent Examiner, Art Unit 1743
December 3, 1999.